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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,551	02/05/2004	David Edwards	000166.0109-US02	2801
26853	7590	10/25/2006	EXAMINER	
COVINGTON & BURLING, LLP ATTN: PATENT DOCKETING 1201 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20004-2401			MATTER, KRISTEN CLARETTE	
			ART UNIT	PAPER NUMBER
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DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/771,551	Applicant(s) EDWARDS ET AL.	
	Examiner Kristen C. Matter	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 2/5/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered as marked on the IDS form.

Specification

The disclosure is objected to because of the following informalities:

- In paragraph 00143, line 1, "FIGS. 17A through 17D" should be --FIGS. 17A through 17C--.
- In paragraph 00144, line 6, "handing chad" should be --hanging chad--.
- In paragraph 00144, line 7, "prong 1600" should be --prong 1620--.
- In paragraph 00145, line 2, and paragraph 00149, line 2, "puncturing device 1630" should be --puncturing device 1600--.
- In paragraph 00151, line 3, paragraphs 00152 and 00153, line 1, and paragraph 00158, lines 1, 3, 5, 6, and 9, "means for indicating readiness 1800" should be --device for emitting powder 1800--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 8, 9, 14, 16, 18, 25, 27, 28, 29, 31, 32, 33, 37, 40, 46, 48, 50, 57, 59, 60 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Snow (US 6,948,494). Snow discloses a medicament container for the administration of dry powder medicament that provides a lancet mechanism for puncturing a container of dry medicament. The lancet mechanism can be seen in Figure 3B. The tapered end 212a of the lancet provides a means for puncturing the medicament container. Furthermore, as the lancet punctures the container, a foil covering is pressed against an upper surface of a lower layer to thereby fold the foil (i.e., hanging chad) out of the flow path so that it will not disrupt the flow of medicament (see column 5, lines 15-20).

Regarding claims 1 and 31, lancet 212 describes the longitudinal prong, surface 212a describes the puncturing surface, the edge between the lancet body 212b and the most distal point of the lancet describes a cutting edge (edge to the inner faces of the two lancets facing each other in Figure 5), and the outer faces of the two lancets seen in Figure 5 describe the planar face opposite of the primary cutting edge. As mentioned earlier, the lancet folds the foil out of the flow path, forming a hanging chad with a hinge coupled to a wall.

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Regarding claims 2 and 32, the point on the distal end of the cutting edge is sharp as seen in Figure 3B and as described for puncturing.

Regarding claims 3 and 33, lancet body 212b describes the base of the prong.

Regarding claims 8 and 39, the lancet is tapered as seen in Figure 3A making the distal end smaller than the proximal end.

Regarding claims 9 and 40, tapered surface 212a describes the angles surface.

Regarding claims 14 and 46, the longitudinal edges are those that line the plantar face and the longitudinal faces are the faces between the longitudinal edges and the cutting edges in Figure 3B of Snow.

Regarding claims 16, 18, 48, and 50, two longitudinal faces are seen lying opposite each other on each lancet disclosed by Snow. Each lancet has two longitudinal edges bordering its plantar face, sharing the edge with the longitudinal face.

Regarding claims 25 and 57, the longitudinal faces disclosed by Snow are substantially planar.

Regarding claims 27-29 and 59-61, the lancet mechanism disclosed by Snow has lancet body 212b and is substantially U-shaped as seen in Figure 3B.

Regarding claim 37, the face disclosed by Snow is substantially planar as seen in Figure 3B.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 6, 7, 10, 11, 12, 13, 15, 17, 19, 20, 21, 22, 23, 24, 26, 30, 34, 35, 36, 37, 38, 41, 42, 43, 44, 45, 47, 49, 51, 52, 53, 54, 55, 56, 58, 62, and 63 are rejected under 35 U.S.C.

103(a) as being unpatentable over Snow.

Regarding claims 4-6, 21-24, 34-36, and 53-56, Snow discloses the claimed invention except for the surface of the edges on the lancet. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the cutting edge sharp, jagged, or serrated, and some or all of the longitudinal edges sharp, jagged, serrated, or blunt, so long as the lancet was able to efficiently open the medicament container, since applicant gives no criticality to the surface of the edges of the prong.

Regarding claims 7, 26, 38, and 58, Snow discloses the claimed invention except for the curvature of the planar and longitudinal faces. It would have been an obvious design choice to one of ordinary skill in the art at the time the invention was made to have made the faces slightly concave depending on the basis of its suitability for the intended use, since applicant gives no criticality to the curvature of the planar or longitudinal faces or discloses that concave surfaces solves a stated problem or provides an advantage.

Regarding claims 10, 30, 41, and 62, Snow discloses the claimed invention except the process by which the lancet mechanism was made. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2nd 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 11-13 and 42-44, Snow discloses the claimed invention except for the material of the lancet mechanism. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made lancet mechanism metal, ceramic, or plastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Furthermore, applicant gives no criticality to the material of the puncturing mechanism.

Regarding claims 15, 17, 19, 20, 47, 49, 51, and 52, Snow discloses the claimed invention except for the number of longitudinal faces and edges and the cross-section of the prong. It would have been an obvious design choice to one of ordinary skill in the art at the time the invention was made to have made the cross-section of the lancet triangle or pentagon, or to have added 4 longitudinal faces and edges on the basis of its suitability for the intended use, since applicant gives no criticality to the number of longitudinal faces and edges or the cross-section of the prong.

Regarding claim 45, Snow does not teach inserting the lancet at least $\frac{3}{4}$ of its length into the capsule. However, the lancet disclosed by Snow performs the same function of piercing a capsule without breaking off the cut portion of the capsule packaging which could then be inhaled by the user. Furthermore, applicant gives no criticality to inserting the prong at least $\frac{3}{4}$ of its length into the capsule. It would have been obvious to one of ordinary skill in the art at the

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time the invention was made to insert a piercing mechanism at least $\frac{3}{4}$ of its length in a device which pierces a capsule along its longitudinal axis such as in Valentini et al. (US 4,995,385).

Regarding claim 63, Snow does not disclose that the foil is folded to an angle of at least 30 degrees with respect to a minor axis. Applicant has not disclosed that opening the chad at least 30 degrees solves any stated problem. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have folded the foil at least 30 degrees for ensuring that the foil does not interfere with air flow of the medicament.

Claims 64, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al. (US 6,298,846) in view of Snow. Ohki et al. teaches a suction type medicator for administering dry medicament from a capsule. The device has a first casing portion 25 that houses a perforating tool 27. Capsule holding section 9 lies within the first casing portion and when the capsule holder 8 is in a closed position (as seen in Figure 8) the capsule is held in place by a circumferential ring defined by capsule fitting groove 6 and capsule holder 8 (see area surrounding capsule K in Figure 8). Mouthpiece 7 describes a second casing portion.

Regarding claim 64, the inhalation portion is defined as the mouthpiece 7 portion with mesh 29 through which medicament passes through for inhalation. Ohki et al. do not disclose the mesh being hemispherical. It would have been an obvious design choice to one of ordinary skill in the art at the time the invention was made to have made the mesh hemispherical for catching oversized particles because the applicant gives no criticality to the aperture region being a hemisphere shape in the disclosure. Furthermore, Ohki et al. does not disclose the details of the perforating tool. It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to have combined lancet mechanism taught by Snow with the device disclosed by Ohki et al. for piercing the capsule.

Regarding claims 65 and 66, the mouthpiece 7 describes the casing and the emitter portion with at least one aperture configured to emit powder. See rejection for claim 64 regarding obviousness for combining Ohki et al. with Snow's lancet mechanism.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Smith et al. (US 6,543,448) discloses an apparatus and methods for dispensing dry powder medicament using a piercing mechanism. Valentini et al. (US 4,995,385) discloses an inhaler with a longitudinally pierced capsule. Ohki et al. (US 5,921,236) discloses a medicine-administering device for nasal cavities with a piercing mechanism. Käfer (US 6,367,473) discloses a powder dispenser with a piercing mechanism. Lockhart et al. (US 6,443,152) discloses a medicament respiratory delivery device with a piercing mechanism. Cavazza (US 4,338,931) discloses a device for the quick inhalation of powder drugs with a piercing mechanism. Roche (US 3,425,414) discloses an inhalant dispenser with a piercing mechanism.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kristen C. Matter
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Art Unit 3771


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10/23/06